

## REMARKS

The Official Action dated December 20, 2007 has been carefully reviewed. Claims 1-11 are pending in the subject application. Claim 12 has been previously canceled. Claims 1-6, 8, and 9 are amended herein.

## OBJECTIONS TO THE DISCLOSURE

The Examiner has objected to the disclosure because the “Summary of the Invention section, i.e., a description of the claimed invention, and the invention of the claims should be commensurate.” The Examiner stated that “non-porous material” is not now claimed and the “openings” recited in claims 5-6 were not described in the Summary. The Examiner referenced MPEP 608.01(d). The Examiner then stated that “at the very least, the structure of the cover and the wound contacting layer and its relationship with respect to the undermined portion of the wound is unclear.” The Examiner then stated that “a clear consistent description of the structure, e.g. the discrete openings’, should be set for the throughout the specification, e.g. the first full paragraph of page 5 [of Applicants’ specification].” The Examiner then referenced MPEP 608.01(o). See page 3, paragraph 4 of the 12/20/07 Office Action.

First of all, in regards to the Summary of the Invention section of the present application, Applicants note that it is stated that the claimed member “*may* be formed from a generally non-porous material” and not that the claimed member must always be formed from such a non-porous material. Accordingly, such a recitation in the Summary of the Invention section is not inconsistent with the current claims of the application. However, for purposes of clarification, Applicants have amended the Summary of the Invention to remove this statement.

In regards to the openings recited in claims 5 and 6 of the present application, Applicants note that the Summary of the Invention section clearly states that “[t]he member may further include a plurality of discrete holes formed in the bottom surface and at least one discrete opening formed in the top surface.” See page 3, lines 7-9 of the present application. The Summary

of the Invention further states that “[t]he channels of the wound contacting layer may extend beyond an outer edge of the cover to define the plurality of discrete openings in an outer peripheral portion of the member” and “[t]he cover may include a plurality of discrete holes in communication with the channels of the wound contacting layer to define the plurality of discrete openings of the member.” See page 3, lines 17-22 of the present application. It is clear, therefore, that the Summary of the Invention section recites the “plurality of discrete openings” recited in claims 5 and 6. Accordingly in view of the amendments and remarks above, the Summary of the Invention section currently provides “a brief summary . . . commensurate with the invention as claimed” as is set forth within MPEP 608.01(d) and withdrawal of this objection is respectfully requested.

In regards to the specification in general and the requested need for a clear, consistent description of the structure throughout the application, Applicants have addressed the Examiner’s concern as noted in the §112 Claim Rejections noted below. Applicants have further amended the first full paragraph of the Detailed Description of the Drawings section starting on page 4, line 20 to recite that the access openings are discrete access openings which include both discrete access channels 62 and discrete access holes 64 as suggested by the Examiner. In view of such amendments, withdrawal of this objection as it applies to the specification is requested.

## CLAIM OBJECTIONS

The Examiner objected to claims 1-11 and noted that “claim 6, line 2 appears to be missing a word or words” and requested that the term “wound contactable” be used throughout claims 1-11 rather than the term “wound contacting.” Applicants have amended claim 6 herein for clarification purposes to remove the phrase “the at least one discrete opening is positioned to engage an undermined portion of the wound.”

In order to speed prosecution of this application, Applicants have also amended claims 1-4, 8, and 9 to change the term “wound contacting” to “wound contactable”, although Applicants do not believe that such an amendment is necessary. First of all, the term “wound contactable” is not used anywhere in the specification of the present application. Secondly, it is

clear to anyone reading the present application that the “wound contacting layer” claimed and described within the specification is a layer of the claimed member which is “able to contact” the wound. Such an amendment is unnecessary and serves only to provide a possibly confusing variety of terms for the same structure. As the Examiner noted within the Specification Objections within 12/20/07 Office Action, the use of a confusing variety of terms for the same thing is not permitted by MPEP 608.01(o). Therefore, in order to comply with the Examiner’s unnecessary request to change the term “wound contacting” to “wound contactable” throughout claims 1-11, Applicants must also amend other portions of the specification, such as the Summary of the Invention section and the Detailed Description of the Drawings section, in order to comply with the Examiner’s own earlier stated request. As such, and only in order to speed prosecution of this application, the Summary of the Invention section and the Detailed Description of the Drawings section have been amended to introduce the term “wound contactable.” Applicants note that these claim amendments are set forth only for the purposes of providing a different claim term apparently preferred by the Examiner and not for purposes of patentability.

#### §112 CLAIM REJECTIONS

The Examiner rejected claims 1-7 under 35. U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner stated that “it is unclear where, at a minimum, ‘at least one discrete opening’, see claim 1, i.e., ‘a’ or ‘the’ ‘plurality . . . openings’, see the dependent claims, is located (e.g., the top surface of the cover only? The top surface of the wound contacting layer beyond the cover? both?) and whether such ‘opening’, and the ‘holes’, see claim 1, and ‘channels’, see claim 2, are one and the same, see claim 2, last two lines, and claims 3-4?” See the first paragraph of page 4 of the 12/20/07 Office Action.

Claim 3 is amended herein to remove the phrase “to define a plurality of the discrete openings” in reference to the channels of the wound contacting layer. This phrase was inconsistent

with claim 1's recitation that the "at least one discrete opening" extends through a top surface of the cover. Claim 4 is amended herein to recite that wherein "the at least one discrete opening comprises a plurality of discrete openings in communication with the channels of the wound contactable layer" and the phrase "to define a plurality of the discrete openings" has been removed. Accordingly, withdrawal of this rejection as it applies to claims 1-7 is respectfully requested.

The Examiner further rejected claims 6-7 under 35. U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In making this rejection, the Examiner stated that claim 6 requires "the at least one discrete opening" be "positioned to engage an undermined portion of the wound." Applicants have amended claim 6 to remove this claim language. Accordingly, withdrawal of this objection as it applies to claims 6 and 7 is respectfully requested.

#### §102 CLAIM REJECTIONS

The Examiner rejected claims 1-3 and 8 under 35 U.S.C. §102(b) as being anticipated by GB 2,329,127 to Heaton et al. (hereinafter Heaton). In making this rejection, the Examiner stated that the claimed discrete holes "are the openings of the cells of open celled foam 73" and that the claimed discrete opening is "[central point] 34 and/or [connector] 35 and/or [aperture] 25" of Heaton and the claimed port is "at least [tubular end] 36 which is configured to communicate with the vacuum source." See page 6, paragraph 10 of the 12/20/07 Office Action. In regards to claim 8, the Examiner stated that "the foam 73, i.e., its interconnecting cells/pores/passages, extends beyond cover 30 to define a plurality of 'channels' in the periphery thereof." See the last four lines of page 7 of the 12/20/07 Office Action.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Thus, a reference does not anticipate a claim if the claim contains any limitation that is neither literally nor inherently present in that reference.

Independent claim 1 is amended herein to recite that “the at least one discrete opening is open at the top surface such that negative pressure is communicated to an undermined portion of the wound through the at least one discrete opening.” Nowhere does Heaton disclose or suggest an opening “extending through a top surface of the cover” which is also “open at the top surface” in order to communicate negative pressure to an undermined portion of wound *through* such an opening. As noted by the Examiner, the flange portion 30 of Heaton includes an aperture 34 and a connector 35 located above the aperture 34 for receiving and connecting a catheter thereto. The aperture 34 is in fluid communication with the tubular portion 36 of the connector 35 which is coupled to a source of suction in order to apply negative pressure to the wound. Aperture 34 is the only opening through a top surface in the flange portion 30. However, the aperture 34 of Heaton is not “open at the top surface.” Rather, as noted above, the connector 35 is positioned above the aperture 34 to provide communication between the negative pressure source and the aperture 34. In other words, the aperture 34 is closed or covered at the top surface of the flange portion 30.

Furthermore, the aperture 34 does not and is not able to “communicate negative pressure to an undermined portion” through the aperture 34 itself because the aperture 34 of Heaton is covered and is not exposed to any wound surface, undermined or otherwise, to communicate negative pressure thereto. The aperture 34 of Heaton is provided to *receive* negative pressure from the vacuum source and not to *communicate* negative pressure to any portion of the wound from the aperture 34 itself. As such, while Heaton may disclose the use of foam pack to pack a wound cavity (via the WO 96/05873 publication incorporated by reference therein), Heaton does not disclose or suggest any cover “coupled to the wound contacting layer” which also includes “at least one discrete opening extending through a top surface of the cover . . . [that is] open at the top surface such that negative pressure is communicated to an undermined portion of the wound through the at least one discrete opening.” Accordingly, because Heaton does not disclose each of the elements reciting in claim 1, Heaton does not anticipate claim 1. As such, withdrawal of this rejection as it applies to claim 1, as well as claims 2 and 3, depending either directly or indirectly from of claim 1, is respectfully requested.

Independent claim 8 is amended herein to recite that the cover includes a “generally planar bottom surface that engages the top surface of the wound contactable layer and cooperates with the channels extending along the top surface of the wound contactable layer to define a plurality of passageways connecting each hole with the port.” Heaton does not disclose or suggest any cover having a “generally planar bottom surface that engages the top surface of the wound contactable layer.” Rather, the flange portion 30 includes a series of projections 32 extending downwardly therefrom which contact the foam pad 73, as shown in FIG. 7 of Heaton. Accordingly, because Heaton does not disclose each of the elements reciting in claim 8, Heaton does not anticipate 8. As such, withdrawal of this rejection as it applies to claim 8 is respectfully requested.

The Examiner rejected claims 1, 2, and 4-7 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,752,794 to Lockwood et al. (hereinafter Lockwood). In making this rejection, the Examiner stated, in particular, that “the cover is 52 which includes, as best understood, at least one “discrete” opening, see 51 or Figure 15, extending through the top surface thereof and the port is at 13 and/or 26 or 70 which is configured to communicate with the vacuums source and in fluid communication with each ‘discrete’ hole the at least one ‘discrete’ opening.” See the paragraph beginning at the bottom of page 8 of the 12/20/07 Office Action.

As noted above, independent claim 1 is amended herein to recite that “the at least one discrete opening is open at the top surface such that negative pressure is communicated to an undermined portion of the wound through the at least one discrete opening.” Nowhere does Lockwood disclose or suggest an opening “extending through a top surface of the cover” which is also “open at the top surface” in order to communicate negative pressure to an undermined portion of wound *through* such an opening. As noted by the Examiner, the cover 52 of Lockwood includes a port (or hole) 51 coupled to a vacuum/irrigation tube 13, as shown in FIG. 3, and alternatively may include multiple ports which are also each coupled to a tube 70, as shown in FIG. 15. These holes 51 through the cover 52 of Lockwood are not “open at the top surface.” Rather, because each hole 51 is coupled to a corresponding vacuum/irrigation tube 13 or 70, these holes 51 are covered by such tubes 13, 70. Furthermore, the holes 51 of Lockwood do not and cannot “communicate negative

pressure to an undermined portion of the wound” because the holes 51 are covered and are not exposed to any wound surface, undermined or otherwise, to communicate negative pressure thereto. The holes 51 of the cover 52 of Lockwood are provided to *receive* negative pressure from the vacuum source and not to *communicate* negative pressure to any portion of the wound from the holes themselves. Therefore, Lockwood does not disclose or suggest any “discrete opening” that is open at the top surface of the cover and particularly does not disclose or suggest any cover which communicates negative pressure to an undermined portion of the wound through such an opening. Accordingly, because Lockwood does not disclose each of the elements reciting in claim 1, Lockwood does not anticipate claim 1. As such, withdrawal of this rejection as it applies to claim 1, as well as claims 2 and 4-7, depending either directly or indirectly from of claim 1, is respectfully requested.

### §103 CLAIM REJECTIONS

The Examiner rejected claims 4-7 and 9-11 under 35 U.S.C. §103(a) as being unpatentable over Heaton in view of PCT Publication No. WO 99/01173 to Ohmstede (hereinafter Ohmstede). In making this rejection, the Examiner references the Abstract of Ohmstede which states that a thickening [12] of the drainage system “is provided on the underside with one or more openings, which open into and cooperate with the openings in the plate-shaped member [11].” The Examiner then stated that “[t]o make the one opening of the suction head/plate shaped member of ‘127 more than one opening would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by ‘173.” See page 11 of the 12/20/07 Office Action.

The Supreme Court in *KSR* reaffirmed that certain principles govern the analysis of obviousness. One such principle is that an examiner “in formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art element [must] identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.” See Memorandum from Margaret A. Focarino, Deputy Commissioner for Patent Operations to

Technology Center Directors (May 3, 2007) (hereinafter “Forcarino Memo”) (quoting *KSR*, 127 S.Ct. at 1741). Another principle the *KSR* court emphasized is the need for the examiner to engage in an explicit analysis of obviousness; as the Court stated: “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, 127 S.Ct. at 1741 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

In the case at hand, respectfully, the Examiner has provided no viable analysis whatsoever as to why the Examiner believes that a person of ordinary skill in the art would combine Heaton and Ohmstede. At best, the Examiner’s statement that “[t]o make the one opening of the suction head/plate shaped member of ‘127 more than one opening would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by ‘173” is pure speculation and conclusory. There is simply no indication why one skilled in the art would combine the teachings from Ohmstede with the suction head of Heaton. Furthermore, the Examiner did not offer “demands known to the design community or present in the market place.” See Forcarino Memo (quoting *KSR*, 127 S.Ct. at 1740). Nor did the Examiner discuss how the “background knowledge possessed by a person of ordinary skill in the art” led the Examiner to conclude there was a reason to combine.” *Id.* Thus, the Examiner has failed to engage in the explicit analysis required by *KSR* and has failed to establish a proper obviousness rejection based on Heaton in view of Ohmstede.

In addition to the fact that the combination of Heaton and Ohmstede is improper, such a combination does not arrive at the invention recited in newly amended claim 9. Claim 9 recites “a second plurality of discrete holes opening through a top surface of the cover *and which are open at the top surface*” and “the second plurality of discrete holes and the plurality of peripheral access channels adapted to communicate negative pressure *directly* to an undermined portion of the wound.” Emphasis added. Nowhere does Heaton disclose or suggest “a second plurality of discrete holes opening through a top surface of the cover and which are open at the top surface . . . [to] communicate negative pressure directly to an undermined portion of the wound.” Ohmstede, which Applicants assert above is not properly combinable with Heaton, does not make up for this



deficiency. Nowhere does Ohmstede disclose or suggest “a second plurality of discrete holes opening through a top surface of the cover and which are open at the top surface” in order to “communicate negative pressure directly to an undermined portion of the wound.” Ohmstede discloses a thickening 12 having openings formed in a bottom surface thereof, and a plate-shaped member 11 is coupled to the bottom surface of the thickening 12, as shown in FIG. 1 of Ohmstede, and includes openings 20 formed therethrough which are exactly aligned with the openings of the thickening 12. Accordingly, all openings 20 of the Ohmstede drainage system are closed openings which are not “open at the top surface . . . [to] communicate negative pressure directly to an undermined portion of the wound.” Each of the holes 20 of the plate 11 is covered by the thickening 12 and is unable to communicate negative pressure directly to any portion of a wound surface. In other words, the holes 20 receive negative pressure from a suction unit 26 coupled to the thickening 12 through a tube 24 and communicate this negative pressure to the foam 23 below. However, the holes 20 do not and cannot communicate this negative pressure directly to a wound surface because they are covered and are not “open at the top surface” as is recited in claim 9. Accordingly, the combination of Heaton and Ohmstede does not arrive at the combination of elements recited in claim 9. Withdrawal of this 35 U.S.C. § 103(a) rejection of claim 9 as well claims 10 and 11, depending either directly or indirectly from claim 9, is respectfully requested.

In regards to claims 4-7, each of these claims depends either directly or indirectly from independent claim 1 and incorporates all of the limitations of the base claim therein. As such, in view of the amendment made to claim 1 and the arguments set forth above in regards to claim 1, the rejection of dependent claims 4-7 is now moot. Furthermore, any arguments specific to claims 4-7 are held in abeyance without prejudice or admission to any assertion made by the Examiner in order to expedite prosecution. Accordingly, withdrawal of this rejection as it applies to claims 4-7 is respectfully requested.

## FURTHER ACTION

In view of the foregoing remarks, the subject application is now deemed to be in condition for allowance, and such action is respectfully requested. If there are any questions or comments that would speed prosecution of this application, the Examiner is invited to call the undersigned at (317) 231-7216. It is respectfully requested that if necessary this paper be considered as a petition for an extension of time sufficient to effect a timely response and that any extension of time fees, as well as any other fees, be charged to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 7175-71858.

Respectfully submitted,

BARNES & THORNBURG LLP

A handwritten signature in black ink, appearing to read "Carli E. Stewart", with a long horizontal flourish extending to the right.

Carli E. Stewart

Attorney Reg. No. 51,058

Indianapolis, IN  
(317) 231-7216  
[carli.stewart@btlaw.com](mailto:carli.stewart@btlaw.com)